Clinical Policy: Lusutrombopag (Mulpleta)

Reference Number: ERX.SPA.321
Effective Date: 03.01.19
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Lusutrombopag (Mulpleta®) is a thrombopoietin (TPO) receptor agonist.

FDA Approved Indication(s)
Mulpleta is indicated for the treatment of thrombocytopenia in adult patients with chronic liver disease who are scheduled to undergo a procedure.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Mulpleta is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Thrombocytopenia (must meet all)**:**

1. Diagnosis of chronic liver disease;
2. Prescribed by or in consultation with a hematologist, hepatologist, or gastroenterologist;
3. Age ≥ 18 years;
4. Recent (within the past 14 days) platelet count is < 50 x 10^9/L;
5. Member is scheduled to undergo an invasive medical or dental procedure within the next 30 days;
6. Mulpleta is not prescribed concurrently with another thrombopoietin receptor agonist (e.g., Doptelet®, Nplate®, Promacta®);
7. Dose does not exceed 3 mg per day (1 tablet per day).

Approval duration: 14 days (no more than 7 total days of treatment)

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Thrombocytopenia

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
TPO: thrombopoietin

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings
None reported

Appendix D: General Information

- Examples of chronic liver disease include: alcoholic liver disease, chronic viral hepatitis (e.g., hepatitis B and C), and nonalcoholic steatohepatitis.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Thrombocytopenia	3 mg PO QD for a total of 7 days Begin dosing 8-14 days prior to a scheduled procedure. Patients should undergo their procedure 2-8 days after the last dose.	3 mg/day

VI. Product Availability

Tablet: 3 mg

VII. References

1. Mulpleta Prescribing Information. Florham Park, NJ: Shionogi, Inc.; April 2020. Available at: https://www.mulpleta.com. Accessed November 15, 2021.
2. Kumar A, Mhaskar R, Grossman BJ, et al on behalf of the AABB (American Association of Blood Banks) Platelet Transfusion Guidelines Panel. Platelet transfusion: a systematic review of the clinical evidence. Transfusion. 2015; 55: 1116-1127.
3. Hayashi H, Beppu T, Shirabe K, Maehara Y, and Baba H. Management of thrombocytopenia due to liver cirrhosis: a review. World J Gastroenterol. 2014; 20(10): 2595-2605.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	09.18.18	02.19
1Q 2020 annual review: no significant changes; references reviewed and updated.	11.02.19	02.20
1Q 2021 annual review: added requirement that Mulpleta is not prescribed concurrently with other thrombopoietin receptor agonists; clarified medical or dental procedure should be invasive per clinical trial inclusion criteria; references reviewed and updated.	11.18.20	02.21
1Q 2022 annual review: no significant changes; references reviewed and updated.	11.15.21	02.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.